PLEASE NOTE: This trial has been registered retrospectively.

Trial Description

Title
Ethicus II - Germany (The End-of-life practices in intensive units around the world study / Germany)

Trial Acronym
Ethicus II - D

URL of the trial
[---]*

Brief Summary in Lay Language
Ethicus II - Germany will assess current EOL practices in Germany as part of a larger, international study (Ethicus II) which assesses current practices in ICUs throughout the world. Fifteen years ago, the European-wide Ethicus study [1] showed that up to 20% of patients die in the ICU, mostly after decisions to limit the intensity of life-sustaining treatments. However, end-of-life decisions and practices varied considerably around Europe. Now, we want to compare how practices have changed in those ICUs that participated in the initial ETHICUS study and in other countries around the world. In the German centers we will carry out additional surveys to evaluate the perception and well-being of the patients’ relatives as well as the treating ICU physicians and nurses to determine risk factors for end-of-life decisions as well as their impact on relatives and staff.

Brief Summary in Scientific Language
Although intensive care units (ICUs) save lives, up to 20% of patients die in the ICU. Most ICU deaths occur after decisions to limit the intensity of life-sustaining treatments. Such decisions affect the patients’ relatives, who bear the burden of losing a loved one and having to fulfill the duties of proxies during decision-making. Up to 30 to 50% of relatives suffer from symptoms of anxiety, depression and posttraumatic stress as long as 3 months afterwards [2,3]. Decision-making also affects ICU medical staff. End-of-life care is stressful for nurses and physicians who also have different roles and responsibilities [4,5]. Poor work environment may increase job-related strain and impair staff wellbeing [5,6,7]. Fifteen years ago, the initial Ethicus study showed that end-of-life decisions and practices varied considerably around the world.

With the Ethicus II study - a prospective, observational study - we want to compare how practices are now and whether they have changed in those ICUs that participated in the initial ETHICUS study. All patients who die or who had a limitation of life-sustaining interventions in the ICU will be included. The total number of patients admitted to each ICU during the study period will be collected.
to ascertain the frequency of end-of-life decisions. All patients will be enrolled into the study anonymously only after IRB approval. Five mutually exclusive categories are defined: Failed cardiopulmonary resuscitation (CPR, i.e. death despite ventilation and cardiac massage); Brain death (i.e. documented cessation of cerebral function and meeting criteria for brain death); Withholding (WH) treatments (i.e. a decision was made not to start or increase a life-sustaining intervention. Decision to not perform CPR (do-not-resuscitate) is classified as withholding therapy); Withdrawing (WD) treatments (i.e. a decision was made to actively stop a life-sustaining intervention presently being given) and Active Shortening of the Dying Process (SDP) which is defined as a circumstance in which someone performed an act with the specific intent of shortening the dying process. In addition, the German centers will also perform a survey among relatives after 3 months to assess their perception and satisfaction with decision-making and care as well as psychological symptoms. A survey will also be conducted among treating ICU physicians and nurses to measure their perception of work environment and their psychological wellbeing. Lastly, a culture-specific survey of the structure of participating ICUs will be performed to assess differences.

Study population- All consecutive adult patients admitted to the ICU who die or have any limitation of life-saving interventions in the ICU for the 6 month study period will be studied prospectively. In the event of end-of-life decisions, characteristics of decision-making will be ascertained from the decision-making physician. Patients will be followed until discharge from ICU, hospital, death, or 2 months from the decision to limit therapy. Main relatives of included patients are included if the patient stayed for longer than 48 hours in the ICU. All ICU nurses and physicians involved in the care of patients are eligible.

Organizational Data

- DRKS-ID: DRKS00010044
- Date of Registration in DRKS: 2016/02/12
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): yes
- Ethics Approval/Approval of the Ethics Committee: Approved
- (leading) Ethics Committee Nr.: 4311-01/15 , Ethikkommission der Friedrich-Schiller-Universität Jena an der Medizinischen Fakultät

Secondary IDs

- Free text: • Intensive Care
  • Dying in the intensive care unit
  • Limitation of life-sustaining treatment in the ICU
Interventions/Observational Groups

Arm 1: All consecutive adult patients admitted to the ICU who die or have any limitation of life-saving interventions in the ICU are observed; all relatives are invited to participate in a postal survey after 90 days; all physicians and nurses in the ICU are questioned once with a staff survey.

Characteristics

- Study Type: Non-interventional
- Study Type Non-Interventional: Observational study
- Allocation: Single arm study
- Blinding: [---]*
- Who is blinded: [---]*
- Control: Uncontrolled/Single arm
- Purpose: Health care system
- Assignment: Single (group)
- Phase: N/A
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): N/A

Primary Outcome

- end of life category

Secondary Outcome

- characteristics of decision-making
- time periods between admission and death/discharge or until end-of-life decision, time period between end-of-life decision and death.
- Emotional exhaustion of ICU nurses and physicians (Maslach Burnout Inventory)
- Perception of work environment by ICU staff in the context of end-of-life practice (validated questionnaire [2])
- Perception of decision-making and EOL Care by relatives after 3 months (validated questionnaire [3])
- Anxiety and depression (measured by Brief-Symptom-Inventory 18) of relatives after 3 months

Countries of recruitment

- DE Germany

Locations of Recruitment
Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/09/15**
- Target Sample Size: **970**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

**Inclusion Criteria**

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
Gender: Both, male and female

Minimum Age: 18 Years

- Maximum Age: no maximum age

Additional Inclusion Criteria

All patients who die or who had a limitation of life-sustaining interventions in the ICU

Exclusion criteria

Patients without limitation of life sustaining therapy who are discharged alive; patients on intermediate care or step down units or normal wards

Addresses

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Sources of Monetary or Material Support

- Institutional budget, no external funding (budget of sponsor/PI)

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Status

- Recruitment Status: Recruiting complete, follow-up complete
- Study Closing (LPLV): 2016/09/30

Trial Publications, Results and other documents

- Background literature 4. Azoulay E, Herridge M. Understanding ICU staff burnout: the show must go on. Am J Respir Crit Care Med 2011; 184: 1099-100

* This entry means the parameter is not applicable or has not been set.
*** This entry means that data is not displayed due to insufficient data privacy clearing.